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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane — Room 1061
Rockville, MD 20852

RE: Docket #98N-0607

To Whom It May Concern:

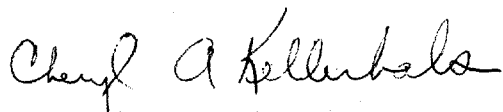
I have been a repeat blood donor for over 20 years and until recently have never been **notified** that my blood donation was deferred. This September I was notified by **LifeSource** that I am ineligible to donate because of a test result done 12 years ago by **United Blood Services**.

I am confused on a variety of issues:

1. According to the information I have read in the background of your docket #98N-0607, in 1985, the Public Health Service (PHS) issued guidelines "that donors testing repeatedly reactive in screening tests for human immunodeficiency virus type 1 (HIV-1) be notified. In addition, PHS recommended that the donor be notified if other tests such as the Western blot were positive." Apparently in 1987, United Blood Services placed me on their donor deferral list, however; they ignored your ruling and never **notified** me. They **also** did a Western blot test the result of which was indeterminate.
2. Furthermore, your docket #98N-0607 states "Notification should include the reason for the permanent deferral, possibilities for re-entry as a donor, and counseling or referral to the donor's physician." In September, 1999, when **LifeSource** informed me of my donor deferral status I received a simple computer print screen with a Dr. Moriarty's scribbling restating that the donor was deferred, with no further explanation. Repeated telephone calls to **LifeSource** resulted in further confusion, hence my Internet research.
3. Your docket #98N-0607 states: "In 1987, PHS recommended that a person be considered to have serologic evidence of HIV infection only after an enzyme immunoassay screening test was repeatedly **reactive** and another test such as Western blot had been performed to validate the results." In my case the Western blot **did not** validate the results of the repeat reactive **elisa** test and results from recent blood donations with **LifeSource** show a negative **anti-HIV-1/2** and state that my blood has "Met all screening criteria". Yet, because of a twelve-year-old **indeterminate** test result they refuse my blood.

Please explain how United Blood Services can ignore your rulings. Also, why is **LifeSource** always advertising blood shortages yet despite the **fact** that I have 'met all screening criteria' they do not want my donation. I am not a "two donations per year" repeat donor, I donate as often as feasible and only when I am in good health. Please advise as to how I can again continue to donate.

Sincerely,



Cheryl A. Kellerhals

98N-0607

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